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REMARKS

I. Status Summary

Claims 1-42 are pending in the present application. As a result of a Restriction Requirement, claims 1-37 have been withdrawn. Accordingly, claims 38-42 are pending and have been examined.

The specification has been objected to by the United States Patent and Trademark Office (hereinafter "the Patent Office") on several bases. First, the Patent Office has objected to the Title, contending that it is not descriptive. Second, the Patent Office asserts that the first line of the specification should be amended to reflect that that the parental application is now U.S. Patent No. 6,300,541. Finally, the Patent Office has objected to the Abstract upon the contention that it contains information that is not directed to the elected invention.

Claims 38-42 have been rejected under 35 U.S.C. § 112, second paragraph, on several bases.

Claims 38-40 have been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the claim contain subject matter that was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains to make and/or use the invention.

Claims 41 and 42 have been rejected under 35 U.S.C. § 102/103 upon the contention that the claims are anticipated by, or in the alternative obvious over, *Stephens et al.* (33 *Crop Sci* 63-66, 1993; hereinafter "Stephens").

The specification and claims 38 and 39 have been amended. Support for the amendments can be found throughout the specification as filed, including particularly at page 36, line 17, through page 38, line 5. Additional support can be found on page 14, line 12, to page 15, line 9, and in the claims as filed.

New claims 43 and 44 have been added by the present amendment. Support for the new claims can be found throughout the specification as filed, including particularly in Example 8 at page 92, line 18, through page 93, line 14. No new matter has been added by any of the amendments to the specification or the claims or by the addition of

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the new claims. Reconsideration of the application as amended and based on the remarks set forth herein below is respectfully requested.

II. Responses to Objections

The specification has been objected to by the United States Patent and Trademark Office (hereinafter "the Patent Office") on several bases. First, the Patent Office has objected to the Title, contending that it is not descriptive. Second, the Patent Office asserts that the first line of the specification should be amended to reflect that that the parental application is now U.S. Patent No. 6,300,541. Finally, the Patent Office has objected to the Abstract upon the contention that it contains information that is not directed to the elected invention.

Response to the Objection to the Title

The Patent Office has objected to the Title of the application upon the contention that it is not descriptive. While applicants do not necessarily agree with the Patent Office's contention, in an effort to facilitate the prosecution of the instant application, applicants have amended the Title as suggested by Examiner Kruse. Accordingly, applicants respectfully submit that the objection has been addressed, and respectfully request that it be withdrawn.

Response to the Objection to the Priority Paragraph

The Patent Office has objected to the specification upon the contention that the first line of the specification should be amended to reflect that that the parental application is now U.S. Patent No. 6,300,541. Applicants have so amended the priority paragraph, and thus believe that the instant objection has been addressed. Applicants respectfully request that the objection be withdrawn.

Response to the Objection to the Abstract

The Patent Office has objected to the Abstract upon the contention that it contains information that is not directed to the elected invention. Applicants respectfully traverse the instant objection.

Applicants respectfully submit that according to M.P.E.P. § 608.01(b), the Abstract is intended as a technical disclosure of the specification, not of the claims.

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Furthermore, § 608/01(b) indicates that "the purpose of the abstract is to enable the United States Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure". As such, applicants respectfully submit that the Abstract would be expected to encompass a broader scope that just the claims in most if not all applications that have been subjected to a Restriction Requirement, as the specification of an application subjected to a Restriction Requirement allegedly discloses more than one invention. Thus, applicants respectfully submit that the Patent Office's basis for this objection is improper.

However, in an effort to facilitate the prosecution of the pending claims, applicants have amended the Abstract to disclose only the subject matter of the elected claims. Applicants respectfully submit that the instant objection has been addressed, and respectfully request that it be withdrawn.

III. Response to Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 38-42 have been rejected under 35 U.S.C. § 112, second paragraph, upon the contention that certain terms and phrases used in the claims render the claims indefinite. After carefully consideration of the rejection and the Patent Office's bases therefor, applicants respectfully traverse the rejection and submit the following remarks.

The Phrase "A Low Density Inoculum"

The first aspect of the instant rejection relates to the recitation in claim 38(a) relates to the assertion that the phrase "a low density inoculum" is relative and does not state the metes and bounds of the claimed subject matter. Applicants respectfully submit that the claims must be read in view of the specification, and given the teachings of the specification and the knowledge of the skilled artisan, applicants respectfully submit that one of ordinary skill in the art would recognize the nature of a "low density inoculum". Thus, applicants respectfully submit that when read in light of the specification, the metes and bounds of the claim are set out by the phrase "low density inoculum".

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Additionally, in an effort to facilitate prosecution of the pending claims, applicants have amended claim 39 to independent form. Thus, claim 39 recites "inoculating soil with a low density inoculum of *Fusarium solani*, wherein the low density inoculum is of about 3×10^3 spore/cm³ soil". Applicants respectfully submit that the amendment to claim 39 further addresses the instant aspect of the rejection.

The Phrase "For a Predetermined Period of Time"

The second aspect of the instant rejection relates to the recitation in claim 38(c) relates to the assertion that the phrase "for a predetermined period of time" is indefinite. Applicants respectfully submit, however, that the phrase "for a predetermined period of time" is not ambiguous on its face. Given the teachings of the specification and the knowledge of the skilled artisan, applicants respectfully submit that one of ordinary skill in the art would recognize how long to grow said plant in said soil in a greenhouse in order to isolate *Fusarium solani*-infected tissue from said plant as required by the method claimed in claim 38. Applicants respectfully submit that the specification as filed also discloses various "predetermined periods of time" that can are appropriate for use in the instant method.

Accordingly, applicants respectfully submit that when claim 38 is viewed in light of the specification and the knowledge of the skilled artisan, the phrase "for a predetermined period of time" is not indefinite.

However, in an effort to facilitate prosecution of the pending claims, applicants have amended claim 38(c) to delete the objected to phrase. Applicants respectfully submit that the amendment to claim 38 addresses the instant aspect of the rejection.

The Term "Determining"

The third aspect of the instant rejection relates to the recitation in claim 38(f) relates to the assertion that the term "determining" is indefinite. The Patent Office asserts that it is unclear what the metes and bounds of "determining" are in relation to disease severity and/or infection severity and fungal colony forming units. Applicants respectfully submit, however, that subsection (f) of claim 38 recites a step wherein the disease and/or infection severity is scored so that it can be compared in step (g). Applicants further respectfully submit that the specification as filed discloses art-

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recognized techniques for performing this scoring, including those techniques disclosed in Njiti *et al.*, 1996 for scoring leaf yellowing and necrosis on a scale of 1 to 9 and Njiti *et al.*, 1997 for scoring infection severity as a 0-100% scale for root segments yielding fungal colonies. Accordingly, applicants respectfully submit that upon review of the instant specification, one of ordinary skill in the art would recognize the metes and bounds of claim 38(f).

However, in an effort to facilitate prosecution of the pending claims, applicants have amended claim 38(f) to recite "scoring at least one of disease severity and infection severity in said plant using the number of said fungal colony forming units". Support for the amendment can be found throughout the specification as filed, including particularly in Example 1 at page 36, line 17, through page 38, line 5. Applicants respectfully submit that the amendment to claim 38(f) addresses the instant aspect of the rejection.

Claim 38, Subsection (g)

The Patent Office has raised two objections related to subsection (g) of Claim 38. The first relates to the use of the term "and/or". The second relates to the phrase "to identify a correlation". Applicants respectfully submit that claim 38(g) has been amended to recite "correlating at least one of said disease severity and said infection severity to at least one of disease severity and infection severity data from genetic markers associated with soybean sudden death syndrome resistance, wherein a statistically significant correlation indicates presence of soybean sudden death syndrome resistance in said soybean plant". Applicants respectfully submit that the amendments to claim 38, subsection (g), address both aspects of the instant rejection.

Claim 38, Generally

Claim 38 has also been rejected under this section upon the contention that the result of the method does not support the preamble of the claim. Applicants respectfully submit that Claim 38 has been amended to recite, *inter alia*, "a method of determining the presence of soybean sudden death syndrome resistance in the soybean plant in a greenhouse setting, the method comprising the steps of... (g) correlating at least one of said disease severity and said infection severity to at least one of disease severity and

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infection severity data from genetic markers associated with soybean sudden death syndrome resistance to identify a correlation, wherein a statistically significant correlation indicates presence of soybean sudden death syndrome resistance in said soybean plant. Support for the amendment can be found in the specification as filed, including particularly at page 14, line 12, to page 15, line 9. Applicants respectfully submit that the amendments to the preamble and subsection (g) harmonize the preamble and the outcome sought by the recited method.

Accordingly, applicants respectfully submit that the instant rejection of claim 38 has been addressed. Applicants further respectfully submit that the amendments to claim 38 render the rejection of claim 40 moot, as claim 40 depends from claim 38. Similarly, claim 39 has been amended to incorporate directly the elements of claim 38, and thus applicants respectfully submit that the rejection of claim 39 has been addressed. Applicants respectfully submit that claims 38-40 are now in condition for allowance.

The Phrase "Characterizing Resistance"

Claim 41(d) has been rejected upon the assertion that the phrase "characterizing resistance" is unclear because it is unclear how this is related to root infection severity. Applicants respectfully submit that claim 41 recites *inter alia*, a method of characterizing resistance to soybean sudden death syndrome in a soybean plant by: (a) isolating roots from a soybean plant infected by *Fusarium solani*; (b) culturing the root on a culture plate including a restrictive growth medium that provides for slow fungal growth and restricted bacterial growth; (c) determining root infection severity by statistically evaluating the number of *Fusarium solani* colony forming units on said culture plate; and (d) characterizing resistance to soybean sudden death syndrome in said soybean plant based on said determined root infection severity. Stated another way, applicants respectfully submit that when root infection severity is determined through the statistical evaluation of step (c), this allows the resistance to SDS to be characterized. As taught in the specification as filed, root infection severity relates to the resistance phenotype, and thus applicants respectfully submit that when read in light of the specification as

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filed, the metes and bounds of "characterizing resistance" based on root infection severity is clear.

Accordingly, applicants respectfully submit that the rejection of claim 41(d) has been addressed, and that the claim is in condition for allowance at this time.

The Phrase "Determining a Level of Resistance"

Claim 42 has been rejected as indefinite upon the contention that the metes and bounds of "determining a level of resistance" are unclear, as is how the method step is accomplished. Applicants respectfully submit that the claims must be read in view of the specification, and further that given the teachings of the specification and the knowledge of the skilled artisan, one of ordinary skill in the art would understand the metes and bounds of "determining a level of resistance". Additionally, applicants respectfully submit that the specification as filed, when viewed from the perspective and with the knowledge of the skilled artisan, teaches how to determine a level of resistance. Thus, applicants respectfully submit that the instant rejection has been addressed, and respectfully request that it be withdrawn.

Summarily, then, applicants respectfully submit that as a result of the amendments to the claims in combination with the remarks presented herein, the rejections of claims 38-42 under 35 U.S.C. § 112, second paragraph, have been addressed. Accordingly, applicants respectfully submit that claims 38-42 are now in condition for allowance. Applicants respectfully solicit a Notice of Allowance to that effect.

Response to Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 38-40 have been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the claims encompass subject matter that was not described in the specification in such a way as to enable one of ordinary skill in the art to make and use the invention. The Patent Office asserts that the art distinguishes between low and moderate inoculum levels, and further that Njiti *et al.* (41 *Crop Sci* 1726, 2001) taught that at low inoculum levels, about 20% of field susceptible lines were identified as resistant. The Patent Office also asserts that applicants provide

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limited guidance for how to use the claimed method...only teach[ing] said method using a known SDS resistant soybean cultivar 'Forest', a known SDS susceptible soybean cultivar 'Essex' and progeny thereof. The art teaches that correlating field resistance for SDS using a greenhouse method requires a moderate inoculum rate of $4-5 \times 10^3$ spores/cm³ of soil, and that at low inoculum levels about 20% of field susceptible lines were identified as resistant.

Official Action at page 5, citing Njiti *et al.* (41 *Crop Sci* 1726-1731, 2001; hereinafter "Njiti *et al.*, 2001"). This leads the Patent Office to assert that "given the limited teachings of Applicant and the teachings of the art it would have required undue trial and error experimentation by one of skill in the art at the time of Applicants' invention to screen through a myriad of soybean lines both susceptible and resistant to SDS using a low inoculum level in order to use the invention as claimed". Official Action at pages 5-6.

After carefully reviewing the rejection and the Patent Office's bases therefor, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants respectfully submit that as a matter of Patent Office practice, the burden rests upon the Patent Office to establish a *prima facie* case of a failure to comply with 35 U.S.C. § 112, first paragraph, with respect to the invention described and claimed in applicants' presumptively enabling patent application. See In re Marzocchi, 58 C.C.P.A. 1069, 439 F.2d 220, 169 U.S.P.Q. 367 (C.C.P.A. 1971). Indeed, 35 U.S.C. §112, first paragraph, requires no more than a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims, and this requirement has clearly been met in the instant U.S. patent application.

In In re Wands, the Court of Appeals for the Federal Circuit as announced eight factors that must be taken into consideration for determining whether undue experimentation would be necessary to practice the invention. In re Wands, 858 F.2d 731 (Fed. Cir. 1988). These so-called *Wands* factors include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the

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prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicants respectfully submit that when these factors are considered together, they clearly indicate that the specification as filed provides a fully enabling disclosure as to claims 38-42. For example, applicants respectfully submit that the quantity of experimentation that would be required to practice the instant invention is merely that which would be expected to test the resistance to SDS in soybeans. Furthermore, the specification contains numerous working examples that show the exact procedures to be followed in performing such tests.

Continuing with the instant rejection, the Patent Office cites Nijiti et al., 2001 for the proposition that it would require undue experimentation to "screen through a myriad of soybean lines both susceptible and resistant to SDS using a low inoculum level". Furthermore, applicants respectfully submit that even assuming *arguendo* that Nijiti et al., 2001 does teach that at low inoculum levels about 20% of field susceptible lines were identified as resistant, this does not indicate that undue experimentation would be needed to screen any two soybean lines using a low inoculum level. Rather, the specification teaches how to screen soybean lines, and the extent of experimentation that would be necessary to screen any two lines is precisely the same in each case. Even assuming *arguendo* that 20% of the experiments might give imperfect results, this does not imply that the experimentation necessary to perform the method is undue.

Summarily, then, applicants respectfully submit that the Patent Office has not met its burden in establishing a *prima facie* case of a lack of enablement with respect to claims 38-40. Applicants respectfully request that the rejection of claims 38-40 under 35 U.S.C. § 112, first paragraph, be withdrawn, and the claims allowed at this time.

Response to Rejection Under 35 U.S.C. §§ 102/103 as obvious over Stephens et al.

Claims 41 and 42 have been rejected under 35 U.S.C. § 102(b), or in the alternative under 35 U.S.C. § 103(a), upon the contention that the claims are anticipated by and/or obvious over Stephens et al. (33 *Crop Sci* 63, 1993; hereinafter "Stephens et al."). The Patent Office contends that Stephens et al. discloses a method of characterizing resistance to soybean SDS in a soybean plant comprising isolating roots

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from a soybean plant infected by *Fusarium solani*, culturing the root on a culture plate including a restrictive growth medium containing tetracycline, determining "root infection severity by evaluating the colony forming units on said culture plate" and characterizing resistance to soybean SDS in said soybean plant and determining a level of resistance to SDS in the soybean plant. After careful consideration of the rejection and the Patent Office's bases therefor, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants respectfully submit that the Patent Office concedes that Stephens et al. does not teach statistically evaluating the number of colony forming units on the culture plate. Applicants respectfully submit that claim 41 recites the following:

41. A method of characterizing resistance to soybean sudden death syndrome in a soybean plant, the method comprising the steps of:

- (a) isolating roots from a soybean plant infected by *Fusarium solani*;
- (b) culturing the root on a culture plate including a restrictive growth medium that provides for slow fungal growth and restricted bacterial growth;
- (c) determining root infection severity by statistically evaluating the number of *Fusarium solani* colony forming units on said culture plate; and
- (d) characterizing resistance to soybean sudden death syndrome in said soybean plant based on said determined root infection severity.

Applicants respectfully submit that since the Patent Office concedes that subsection (c) of claim 41 is not taught by Stephens et al., it is clear that this reference cannot anticipate the claims. The Patent Office's reliance on Integra Life Sciences does not alter this conclusion, as the cited case requires that "no additional manipulation is required to produce the claimed result". Applicants respectfully submit that the statistical evaluation influences the determination of root infection severity, and thus renders Integra Life Sciences inapplicable. Accordingly, applicants respectfully submit that the rejection under 35 U.S.C. § 102(b) is improper. Applicants respectfully request that the rejection be withdrawn.

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Continuing with the alternative basis for the instant rejection, applicants respectfully submit that in order to render a claim obvious under 35 U.S.C. § 103(a), the cited reference(s) must disclose or suggest each an every element of the claim, as well as motivate the skilled artisan to modify the reference(s) as suggested by the Patent Office to arrive at the claimed invention with a reasonable expectation of success.

Applicants respectfully submit that the Patent Office has not met its burden of establishing a *prima facie* case of obviousness over the cited reference because the cited reference does not provide a motivation to statistically evaluate the number of CFU. Indeed, the Patent Office has offered no basis for the assertion that "such a method step does not appear to teach a significant difference from the method taught by Stephens for characterizing resistance to soybean SDS". Applicants respectfully submit that to support its rejection, the Patent Office has the burden of providing a reasoned explanation for this contention. Applicants respectfully submit that the Patent Office offers no such reasoned explanation.

In summary, applicants respectfully submit that the Patent Office has not presented a *prima facie* case of obviousness of claims 41 and 42. Thus, applicants respectfully submit that claims 41 and 42 are in condition for allowance, and respectfully request a Notice of Allowance to that effect.

IV. Discussion of the New Claims

New claims 43 and 44 have been added. New claims 43 and 44 have been added by the present amendment. Support for the new claims can be found throughout the specification as filed, including particularly in Example 8 at page 92, line 18, through page 93, line 14. As such, no new matter has been added by the addition of the new claims.

New claims 43 and 44 are believed to be patentable over the art cited against claims 38-42 for the reasons described hereinabove with regard to claims 38-42. Additionally, claims 43 and 44 recite that the restrictive growth medium comprises one or more fungicidal antibiotics and one or more bacteriocidal or bacteriostatic antibiotics.

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Applicants respectfully submit that none of the cited art discloses the use of a medium that contains both anti-fungal and anti-bacterial agents.

Accordingly, applicants respectfully submit that claims 43 and 44 are in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

JENKINS, WILSON & TAYLOR, P.A.

Date:

09/09/2004

By:

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AAT/_CPP/ptw

Enclosure: Clean Version of Abstract on a Separate Sheet

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